

The Society of Thoracic Surgeons
Comments for the Public Record
House Committee on Ways and Means, Subcommittee on Social Security Hearing
The Accuracy and Uses of the Social Security Administration's Death Master File
February 2, 2012

The Society of Thoracic Surgeons (STS) is the largest organization representing cardiothoracic surgeons in the United States and the world. We are writing in response to the House Committee on Ways and Means – Subcommittee on Social Security hearing on “The Accuracy and Uses of the Social Security Administration’s Death Master File.”

Founded in 1964, STS is a not-for-profit organization representing more than 6,100 surgeons, researchers, and allied health care professionals who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest. Thank you for considering these comments as you focus on this most important issue.

We are writing to express our concern and request your assistance with an issue of critical importance to our ongoing, cutting-edge, health care quality improvement efforts. As you are aware, beginning November 1, 2011, the Social Security Administration (SSA) rescinded its policy of sharing death reports that it receives from individual states. Reportedly, under the revised opinion of the SSA general counsel, SSA will only share state-originated death information with Federal agencies. This change in policy could compromise the ability of STS, and other medical specialties that utilize clinical registries, to successfully monitor long term patient outcomes. This information has been of vital importance to physicians and researchers who want to evaluate the success of medical interventions and who want to track other medical and public health related trends.

Linking clinical registries to the Social Security Death Master File (SSDMF) allows for the verification of “life status” of patients who otherwise would be lost for follow up after their treatment. Research based on this information helps physicians to advise today’s patients and families and help them with decision-making. Outcomes data gives patients confidence in their medical interventions and demonstrates to patients and their families the durability and long-term benefits of medical procedures. These data also help medical societies when providing information to policymakers and regulators. For example, data can be used in research comparing the long-term effectiveness of alternative treatment strategies. It also has the potential to generate clinical and longitudinal comparative effectiveness research on a national level that can be evaluated based on patient demographics.

Utilizing these data, we have been able to link and follow patients who have had multiple operations in different institutions, perform long-term follow-up of repeat hospital admissions and additional procedures, and generate Kaplan-Meier survival curves. Physicians have also used these data to evaluate their respective outcomes against the national standard. Research of this sort is already the foundation of research on the safety and effectiveness of medical products and national payment and coverage decisions. (See attached for more information on the STS Database.)

As a medical society, STS has long advocated for the protection of patients' and our members' privacy. The STS Database upholds rigorous privacy protocols and is fully compliant with Health Insurance Portability and Accountability Act (HIPAA) requirements and Federal Common Rule protections for human subjects research.

We respect that Chairman Johnson has introduced H.R. 3475 in order to help to protect individuals' personal information. However, we request that the Congress restore access to all the data in the SSDMF for certain types of medical research that meets established privacy standards and exempt that research from the additional restrictions proposed under H.R. 3475. To that end, we have proposed the following change to the amendment to section 205(r) of the Social Security Act contained in H.R. 3475:

Section 205(r) of the Social Security Act (42 U.S.C. 405) is amended--

(1) in paragraph (5) by striking 'for statistical and research activities' and all that follows and inserting 'for law enforcement, tax administration, and statistical and research activities conducted by Federal agencies and for statistical and research activities conducted by State agencies, *as well as for other statistical and research activities conducted by medical, scientific, or public health researchers in accordance with the Federal Common Rule [46 C.F.R. § 46.101] and/or the applicable privacy and security rules issued under the Health Information Portability and Accountability Act of 1996 [45 C.F.R. Pt. 164 and § 512(i)], and subject to review and approval by an institutional review board registered with the Department of Health and Human Services Office of Human Subjects Protection and/or the Food and Drug Administration and accredited by the Association for the Accreditation of Human Subjects Research Protection Programs.*'; and

STS greatly appreciates the opportunity to offer these comments for the Committee's consideration. We look forward to working with you to achieve our mutual goal of protecting American's privacy and identities while ensuring that innovations in health care quality and technology are able to flourish. Please contact Phil Bongiorno, STS Director of Government Relations, at (202) 787-1221 or pbongiorno@sts.org if you have any questions.

Background

In January 2008, in compliance with HIPAA, STS began to access the SSDMF in order to track long-term survival among cardiothoracic surgical patients. The SSDMF complements the STS Database by providing information about short-term and long-term survival. Linking STS Data to the SSDMF allows researchers to ascertain “life status” of patients who have undergone cardiothoracic surgical procedures.

About the STS Database

STS has long been at the forefront of efforts to improve healthcare quality. The STS National Database was established in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. There are three components to the STS National Database, each focusing on a different area of cardiothoracic surgery—

- Adult Cardiac Surgery Database;
- General Thoracic Surgery Database; and
- Congenital Heart Surgery Database (Anesthesiology may also participate in the Congenital Heart Surgery Database).

The component databases provide participants with opportunities for quality improvement. The Society has developed quality performance measures in all three sub-specialties of surgery and these measures have either been endorsed or are in the process of being considered for endorsement by the National Quality Forum. By collecting outcomes data for submission to the STS National Database, surgeons are committing to improving the quality of care that their cardiothoracic surgery patients receive. The Database has the corollary potential to be a powerful tool for clinical research. Since its inception, more than 100 publications have been derived from Database outcomes. These studies have been published in a variety of professional journals and textbooks and have significantly advanced knowledge in cardiothoracic surgery.

The Database continues to expand with new initiatives. Launched in January 2011, STS Public Reporting Online enables Database participants to voluntarily report to the public their heart bypass surgery performance. Overall composite star ratings as well as their component ratings are listed on www.sts.org for more than 250 Database participants. The Adult Cardiac Surgery Database, now containing more than 4.5 million surgical records, represents an estimated 94 percent of all adult cardiac surgery centers across the U.S. With the success of participation nationally, in 2011 STS launched an initiative to accommodate Database participation worldwide by including international participants in the Adult Cardiac Surgery Database.

In general, the STS National Database provides:

- A standardized format for examining the care of patients undergoing cardiothoracic operations;
- A tool that can be used to target specific areas for clinical practice improvement;
- The ability to obtain an accurate reflection of practice patterns;
- The ability to research the national aggregate data set; and

- The opportunity to participate in a national quality improvement effort for thoracic surgery that has an impact at the local, regional, and national levels.

The Database offers a standardized format for examining the care of patients undergoing cardiothoracic surgical procedures which can be used to target specific areas for clinical practice improvement, obtain an accurate reflection of practice patterns, and conduct research using the national aggregate data set. Many third-party payers, major corporate purchasers of health care, hospitals, health care systems and states now require monitoring of outcomes and participation in quality improvement programs; participation in the Database fulfills these requirements.

STS envisions a health care system that reinforces meaningful quality improvement initiatives, including the acquisition and use of risk-adjusted reliable outcomes and clinical effectiveness data, and reward physicians for improved outcomes. Successful implementation relies on the integration of clinical and administrative data, allowing researchers to monitor the cost of care over time and provide an assessment of clinical and cost effectiveness, including issues related to new technologies and devices. However, only a clinical database with a sufficient volume of clinical records can be credibly risk-adjusted for case mix to yield accurate and comparable findings.

STS has successfully linked its clinical data with Centers for Medicare and Medicaid Services (CMS) MEDPAR information and the SSDMF to obtain longitudinal outcomes data for a wide array of cardiothoracic surgery operations. The ability to link clinical data with administrative data has opened up important new ways to assess the effectiveness of treatment options and offered new avenues for medical research. Clinical data yield sophisticated risk-adjustment assessments, while administrative data provide information on long-term outcomes such as mortality rate, readmission diagnoses, follow-up procedures, medication use, and costs. Linked data are also useful in conducting comparative effectiveness research.

TVT Registry

In addition, STS has recently undertaken to develop the National TVT Registry. The TVT Registry is the result of an ongoing collaboration between STS and The American College of Cardiology in support of Transcatheter Aortic Valve Replacement (TAVR) introduction in the United States. It was also developed in collaboration with the FDA and CMS, with input from The Society for Cardiovascular Angiography and Intervention (SCAI) and The American Association for Thoracic Surgery (AATS).

Approved by the FDA for use in the United States in November 2011, TAVR technology is now an option for elderly patients with aortic stenosis who are too sick, frail, or high risk for conventional surgical therapy. The TVT Registry will capture and house patient demographics, procedure details, and facility and physician information. This standardized, evidence based data source will offer much insight into clinical practice patterns and patient outcomes. The TVT Registry serves as the main repository for all clinical data related to TAVR and is positioned to incorporate additional catheter-based procedures that have yet to come to market in the United States. The TVT Registry was designed to be linked to the SSDMF and CMS databases in order to track long term outcomes. Physician participation in such a clinical registry was a condition of FDA approval of the Edwards Lifesciences SAPIEN device and is expected to be a condition for Medicare reimbursement for TAVR procedures.

